DETAILED ACTION

Status of the Claims

1. Claims 1-6, 8, 12-15, 27, 28 and 33-38 are pending.

Applicants' amendment filed December 10, 2007 is acknowledged. Applicants' response has been fully considered. Claims 1, 12, 27 and 28 have been amended, claims 25, 26 and 29-32 have been canceled, and new claims 33-38 have been added. Therefore, claims 1-6, 8, 12-15, 27, 28 and 33-38 are examined.

2. A telephone interview was conducted with Attorney Nancy Johnson on November 13, 2007 (See attached Interview Summary).

Withdrawn Claim Objections

3. The previous objection to claims 25-28 and 31-32, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claims, and applicants' response at page 6 in the amendment filed December 10, 2007.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 27 and 28 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 6 in the amendment filed December 10, 2007.

Withdrawn Claim Rejections - Obviousness Type Double Patenting

5. The previous rejection of claims 1-6, 8, 12-15 and 25-26 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. patent 6,500,798, is withdrawn in view of applicants' amendment to the claims, applicants'

cancellation of the claims, and applicant's response at page 7 in the amendment filed December 10, 2007.

6. The previous rejection of claims 1-6, 8, 12-15 and 25-26 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. patent 6,903,068, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicant's response at pages 7-8 in the amendment filed December 10, 2007.

7. The previous rejection of claims 1-6, 8, 12-15, 25-26 and 31-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. patent 7,119,064, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicant's response at pages 8-9 in the amendment filed December 10, 2007.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 27-28 and 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-28 and 33-38 are indefinite because of the use of the term "toxic effect of β-amyloid" or "toxic effect of retinoic acid". The term cited renders the claim indefinite, it is not clear what toxic effect the β-amyloid or retinoic acid has. Claims 33-38 are included in the

rejection for being dependent of a rejected claim and not correcting the deficiency of the claim from which they depend.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 27 and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Leszek *et al.* (Archivum Immunologiae et Therapiae Experimentalis 47, 277-385 (1999); listed in the IDS filed 11/29/06).

Leszek *et al.* teach the plaques in the Alzhemer's disease (AD) patients represent β-amyloid deposits, which play a key role in the pathogenesis of AD (page 378, left column); and the use of colostrinin (100 μg per tablet, every second day) in the treatment of Alzhemer's disease (AD) patients, eight of 15 AD patients treated with colostrinin improved, and in 7 others the disease had stabilized (pages 380-382; Tables 2-3; Fig. 2; claims 27 and 33-35). Since the claims do not define the toxic effect of β-amyloid, and the claims encompass an *in vivo* treatment, the effect caused by the plaques of β-amyloid deposits in the Alzhemer's disease (AD) patients would be the toxic effect of β-amyloid, which meets the criteria of claimed invention.

New Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-6, 8, 12-15, 27-28 and 33-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-13 and 19-22 of co-pending application 11/509,979 (based on the amendment filed November 27, 2007). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 8, 12-15, 27-28 and 33-38 in the instant application disclose a method for inhibiting apoptosis, a method for protecting against DNA damage, or a method of reducing the toxic effect of β-amyloid or retinoic acid on a cell, the method comprising determining an effective amount of an apoptosis inhibitor or a compound in the cells, and contacting the cell with the effective amount of an apoptosis inhibitor or a compound selected from the group consisting of colostrinin and a constituent peptide of colostrinin (i.e., SEQ ID NO:1-8). This is obvious variation in view of claims 10-13 and 19-22 of the copending application which disclose a method for inhibiting apoptosis, a method for protecting against DNA damage, or a method of reducing the toxic effect of β-amyloid or retinoic acid on a cell, the method comprising contacting the cell with an effective amount of an apoptosis inhibitor or a compound, wherein the apoptosis inhibitor or the compound is colostrinin or a constituent peptide of colostrinin (SEQ ID NO:1-34). Both sets of claims are directed to a method for inhibiting apoptosis, a method for protecting against DNA damage in a cell, or a method of

reducing the toxic effect of β-amyloid or retinoic acid on a cell, by contacting the cell with an effective amount of colostrinin or a constituent peptide of colostrinin (e.g., SEQ ID NO:1-8). Therefore, claims 1-6, 8, 12-15, 27-28 and 33-38 in instant application and claims 10-13 and 19-22 of the copending application are obvious variations of a method for inhibiting apoptosis, a method for protecting against DNA damage in a cell, or a method of reducing the toxic effect of β-amyloid or retinoic acid on a cell, by contacting the cell with an effective amount of colostrinin or a constituent peptide of colostrinin (e.g., SEQ ID NO:1-8).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusions

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
February 21, 2008